POC approved 3/25/08 mthorne, HFS III

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	NVN470ASC	A. BUILDING _____ B. WING _____	03/05/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
DIGESTIVE HEALTH CENTER	5250 KIETZKE LANE RENO, NV 89511

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 00	INITIAL COMMENTS This Statement of Deficiencies was generated as the result of a focused state licensure survey conducted at your facility on 3/5/08. The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state or local laws. The state licensure survey was conducted in accordance with Chapter 449, Surgical Centers for Ambulatory Patients. The following deficiencies were identified.	A 00		
A 10	NAC 449.980 Administration The governing body shall ensure that: 7. The center adopts, enforces and annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, including an organization chart. These policies and procedures must: (a) Be approved annually by the governing body. This Regulation is not met as evidenced by: Based on observations and policy review on 3/5/08, the governing body failed to enforce its policy on the sterilization of reusable biopsy forceps. Findings include: The policy titled "Endoscopic Equipment - Care and Cleaning" was reviewed. The policy indicated that after the metal biopsy forceps were	A 10	RECEIVED MAR 19 2008 BUREAU OF LICENSURE AND CERTIFICATION CARSON CITY, NEVADA **A 10** **The Endoscopic Equipment-Care & Cleaning policy# C7.11 has been revised to include stronger language regarding proper cleaning and sterilization, specifically of the forceps. (Exhibit A10-1) The staff was in-serviced on the policy initially on 3/6/08 and re-inserviced on 3/19/08. A competency on the Care and Cleaning of Endoscopic equipment will be developed by the center director and implemented on 3/19/08 and annually thereafter. The center director will verify compliance/adherence to policy by silent observation in 30 days.**	

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Theresa Brandt	Administrator	3/19/2008

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A 10	Continued From page 1 processed, they were to be placed in an autoclave package with the forcep jaws opened. Twenty-one sterile packages containing reusable biopsy forceps were observed. The jaws of seventeen biopsy forceps were closed. Severity: 2 Scope: 2	A 10		
A 64	NAC 449.9812 Program for Quality Assurance 2. The program for quality assurance must include, without limitation: (g) Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing: (1) The clinical performances of members of the staff who are health care practitioners. This Regulation is not met as evidenced by: Based on observation and interview on 3/5/08, the facility failed to assess for the clinical performance of staff who failed to follow the manufacturer's guidelines regarding patient return electrodes. Findings include: Three procedure rooms were inspected at 9:00AM. Each room contained an electrocautery unit. Opened patient return electrodes (out of their packages) were observed plugged into each electrocautery unit. An endoscopic technician reported that staff would open the wrapper and plug in the electrode so that they were ready in	A 64	**A 64** Per our policy C2.10 (Exhibit A64-1) and the manufacturers' guidelines, all grounding pad packaging will remain intact/unopened until immediately prior to patient use. All clinical staff were re-educated on the policy on 3/19/08. The center director will verify compliance/adherence to policy by silent observation in 30 days.	

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A 64	Continued From page 2 case the physician needed to use electrocautery. The technician did not know how long the return electrode sitting next to the unit had ben unwrapped. The manufacturer's recommendation was that the patient return electrode packages should be opened just prior to use to prevent the electrode gel from drying out and causing an electrocautery burn. Severity: 2 Scope: 2	A 64		
A 69	NAC 449.9812 Program for Quality Assurance 2. The program for quality assurance must include, without limitation: (g) Procedures for identifying and addressing any problems or concerns related to the care provided to patients using the medical records of the center and any other sources of data that may be useful to identify previously unrecognized concerns, and for assessing the frequency, severity and sources of suspected problems and concerns. The procedures must include, without limitation, procedures for assessing: (6) The procedures used to control infection. This Regulation is not met as evidenced by: Based on record review and interview on 3/5/08, the facility failed to follow procedures to control infections. The facility failed to maintain the Performance Improvement log per the facility's policy and failed to follow the manufacturer recommendations regarding single use items. Findings include: The Performance Improvement log for the monitoring of infections was reviewed. The log contained monthly forms sent to physicians who practiced in the facility. The forms revealed whether a physician had identified a	A 69	**A 69** The Performance Improvement (PI) monthly surveillance forms (Exhibit A69-1) for the monitoring of infections were re-instituted on 3/6/08. The center director will retrospectively collect data from the physician providers from July 2007 to the current date and on-going. The PI committee will analyze the data as previously, and report their findings to the governing body by April 31, 2008, and quarterly thereafter. The center director will monitor monthly for compliance and report to the PI committee and Governing Board quarterly.	

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A 69	Continued From page 3 post-operative infection or complication in one of their patients. The last monthly form in the log was dated June of 2007. During an interview with the administrator, she reported she had stopped sending the forms to the physicians. Instead of sending the forms, the administrator stated she asked the physicians, when she saw them in the facility, whether they had identified any post-operative infections in their patients. The administrator stated the facility had not experienced any reported post-operative infections since June of 2007. Four procedure rooms were inspected. All four rooms contained multiple suction polyp traps not in their original wrappers. A registered nurse reported the facility re-sterilized the suction traps after use. An original wrapper was located and inspected. The wrapper indicated the suction traps were for single use only and were not to be reused. Bite blocks were found in each procedure room. The bite blocks were not in their original wrapper. An endoscopy technician reported the facility re-sterilized the bite blocks after use. An original wrapper was located and inspected. The wrapper indicated the bite blocks were for single patient use. An initial inspection of the facility revealed that procedure rooms were fitted with two wall suction units. These units were hard plastic cannisters with inner soft plastic liners. During an interview the charge nurse confirmed that one suction unit was to be used for endoscopy procedures and the other suction unit was to be used for oral suctioning. The second suction unit could be used as an additional endoscopy suction if it was needed. She confirmed that the inner suction	A 69	**A 69** As per policy# C7.4, items labeled as "Single Use" (specifically bite blocks, polyp traps, and suction liners) will be disposed of after each patient. (Exhibit A69-2) A staff and physician in-service has been conducted by the center director on 3/6/08 for staff and on 3/11/08 for the physicians. The center director will verify compliance/adherence to policy by silent observation in 30 days.	

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A 69	Continued From page 4 liners were not changed between patients. The charge nurse stated the inner liners were changed when they were full of secretions. Observations of three procedures involving three separate patients were conducted. These procedures were done sequentially in the same endoscopy room. The first two procedures that were observed were colonoscopies. The third procedure was an endoscopy of the esophagus and stomach. The suction cannister used during all three procedures was not changed. An interview with the technician who performed the cleaning of the room between the procedures confirmed that the cannister liners were not changed between procedures. The technician indicated that she would change the cannister liners when the secretions were at approximately one inch from the inner top of the suction cannister. During an interview, the administrator acknowledged that suction systems could fail and result in a backflow of secretions into a patient. She acknowledged that the practice of not changing the inner liners of the suction cannisters could result in a backflow of secretions into a different patient. Severity: 2 / Scope: 3	A 69	Addendum to A69 Clarification of 'During an interview' as stated on page 5 of 8, 4th paragraph: The state surveyor stated she had been an OR nurse and as such she had observed a suction system allow backflow into a wound during surgery. The administrator at this point acknowledged the surveyor's anecdotal statement.	
A161	NAC 449.9902 Emergency Equipment/Supplies 1. An ambulatory surgical center must be equipped with: (a) A cardiac defibrillator; (b) A tracheostomy set; and (c) Such other emergency medical equipment and supplies as are specified by the members of	A161	A 161 A tracheotomy tray was purchased on 3/12/08 and placed in the crash cart, in addition to the existing quick-trach	

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A161	Continued From page 5 the medical staff. This Regulation is not met as evidenced by: Based on observation and interview on 3/5/08, the facility did not have a tracheostomy set. Findings Include: An observation and examination of the facility's emergency supply cart revealed that there was no tracheostomy set in the cart. The cart contained a "Quiktract trach kit." This kit contained a large bore needle, known as a cricoid needle. This needle was to be inserted into the neck at the cricoid to open an obstructed airway in an emergency. This procedure is not considered a tracheostomy. The charge nurse and the administrator both confirmed that that the "Quiktract" trach kit would not create a tracheostomy. Severity: 2 Scope: 1	A161	**A 161** Continued From page 5 device. All staff and physicians were in-serviced on the tracheotomy tray and its location in the crash cart on 3/12/08. The tracheotomy tray was added to the code cart inventory list (Exhibit A161-1) and will be checked by staff monthly per policy	
A187	NAC 449.9935 Operating and Recovery Rooms 5. Only a registered nurse may function as the circulating nurse in the operating room. This Regulation is not met as evidenced by: Based on interviews on 3/5/08, the facility failed to ensure that there was a sufficient number of registered nurses to circulate every endoscopy case. Findings include: The charge nurse reported that on Mondays and Fridays, an endoscopy technician, Employee #1,	A187	**A 187** There will be one registered nurse per patient per procedure room functioning in the role of circulating nurse. The C2.2 Conscious Sedation policy (Exhibit A187-1) was reviewed with staff on 3/5/08. Procedures will not begin unless an RN circulating nurse is available in attendance. This will be strictly enforced by the charge nurse and the administrator.	

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A187	Continued From page 6 would circulate endoscopy cases due to staffing issues. The charge nurse stated the employee was not a registered nurse, but was a certified nurse's assistant. The charge nurse further reported that when the technician was alone in the operating room with a physician, the physician would inject intravenous medications because the technician was not legally allowed to administer intravenous medications. The administrator verified that Employee #1 functioned as a circulating nurse occasionally so that the circulating nurses assigned to the operating rooms could take breaks. Severity: 2 Scope: 3	A187		
A190	NAC 449.9935 Operating and Recovery Rooms 6. The operating room must be equipped with: (c) Mechanical ventilatory assistance equipment, including, without limitation, a manual breathing bag and a ventilator. This Regulation is not met as evidenced by: Based on observation and interview on 3/5/08, the facility did have a mechanical ventilator. Findings include: An initial tour of the facility and examination of the emergency equipment revealed that the facility did not have a mechanical ventilator on-site. The charge nurse confirmed that the facility did not have a ventilator on the premise. An interview with the administrator revealed that she had a Elder Demand Valve Respirator in her office. Upon examination of the respirator, it was	A190	**A 190** Two Surevent ventilators were purchased on 3/12/08. All staff and physicians were in-serviced on the use and location on the crash cart on 3/21/08. The ventilator was added to the code cart inventory list (Exhibit A161-1) and will be checked monthly per policy. An annual in-service with return demonstration was added to the annual competency training conducted by the center director.	

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A190	Continued From page 7 revealed that this was an oxygen delivery system that required manual management. The Elder Demand Valve when pushed would force oxygen from the connected tank into the face mask, increasing the oxygen and assisting with a deeper respiration. Upon demonstration of the use of the valve, it malfunctioned. The administrator confirmed that this was not a ventilator. Severity: 2 Scope: 1	A190		

Exhibit

A10-1

C7.11 ENDOSCOPIC EQUIPMENT - CARE AND CLEANING

POLICY:

Endoscopic equipment and all reusable equipment will be promptly cleaned and disinfected or sterilized when applicable after each use or when integrity of disinfected or sterilized state is compromised.

POLICY:

To provide a high level disinfection process for endoscopic equipment.

PROCEDURE:

- Physician carries scope in covered containers to equipment room after fitting air-tight cap on light source end of scope.
- Leak test scope before cleaning. Attach leak tester and perform dry leak test first. Manipulate the scope controls so that the scope moves up, down, right and left. Watch for drop in pressure gauge that would indicate a leak. If a large leak is detected, isolate the leaking channel to prevent fluid invasion of the endoscope and proceed with wet leak test. Completely submerge the scope in enzymatic cleaning solution and manipulate the scope controls so that the scope moves up, down, right and left. Watch for air bubbles that would indicate a leak.
- If a leak is detected, maintain pressurized scope and complete cleaning process if pressurization can be maintained safely to prevent fluid invasion. Once processed, prepare scope for shipping. If scope is not able to be processed due to leak size, wipe all accessible exterior areas of scope with disinfectant and notify the Center Director or designee. Ship scope for repair with biohazard warning label alerting repair facility of scope's biohazard risk.
- If no leak is detected, remove detachable parts of scope and continue cleaning process.
- Suction a minimum of 200cc of enzymatic cleaner through scope.
- Hand wash scope exterior, suction button, air/water button and biopsy port covers using toothbrush, sponge and enzymatic cleaner, then rinse with water.
- Brush biopsy channel from forcep insertion port through channel until brush exits the opening at the end of insertion tube. Repeat until free of debris.
- Brush suction channel from suction button opening through opening on light source end until brush exits. Repeat until free of debris.
- Brush suction channel from suction button opening until meeting resistance. Repeat until free of debris.
- Attach suction and air/water cover. Loosely coil endoscope and place in Custom Ultrasonic (CU) Bay. Attach connectors following manufacturer's recommendations. Add 30cc detergent approved by CU and proceed to process the endoscopy following manufacturer's recommendation.
- At the completion of the processor's cleaning cycles, attach a syringe with 30cc of 70% alcohol for each endoscope and purge through the CU processor. Follow by turning on the air switch until channel is cleared of fluid.

- Remove air-tight cap, remove suction and air/water cover. Replace suction and air/water buttons if scope needed for immediate use.
- If not needed immediately, hang scope in Clean Utility area, being careful not to allow tip to swing against the wall of sides of cabinet.

Biopsy Forceps, Endoscopic Scissors, and Savary Guidewire:

Exhibit A10-1

- Soak in enzyme cleaner for 2 minutes, keeping forceps jaws open. Hand wash with washcloth and toothbrush.
- Rinse in tap water.
- Place in Ultrasonic cleaner and run 10 minutes, then rinse with tap water.
- Towel dry and place in paper peel package with instrument jaws open.
- Place in steam sterilizer with indicator on pouch cycle.
- When package is thoroughly dry, return to room.
- Packages containing forceps are to be inspected prior to use verifying jaws are open. If closed DO NOT USE but return for re-sterilization.

Maloney Dilators:

- Manually clean dilators with enzyme cleaner and rinse with water.
- Disinfect for 20 minutes. Rinse with water and towel dry.

Savary Dilators:

- Manually clean outside of dilator using enzyme cleaner.
- Suction internal channel from tapered end with enzyme cleaner.
- Brush internal channel.
- Process Savary Dilator in CU bay using adapters.
- Dry channel, using 70% alcohol followed with forced air.
- Store in dry, clean cabinet

Water Bottles for Scopes and Bicap:

(Scope bottles disinfected each evening, Bicap bottle after each use.)

- Soak bottle and lid in disinfectant 20 minutes, then rinse bottles thoroughly in water.
- Water bottle lids are flushed with 70% alcohol using a syringe and processed in the autoclave at the end of every day.
- Scope bottles should be refilled with sterile water every a.m.
- Bicap bottle is replaced on cart and only filled with water at time of use.

Enzyme Cleaner:

- Daily put 30cc (1oz) of enzyme cleaner per gallon of water in pan or sink for scope cleaning and in hopper for presoaking all other accessories.
- Empty at the end of workday or any time solution is visibly dirty.
- Wipe empty sinks and surrounding counter tops with AQ+ disinfectant daily.

Ultrasonic Cleaner:

- Daily fill tank 2/3 full with fresh tap water and add 60cc of enzyme cleaner.
- At end of workday, or when visibly dirty, empty tank and wipe dry.

Disinfectant:

- Solution should be changed approximately every 14 days. If level gets too low, additional solution should be added.
- Test MEC every day and document in logbook. If solution fails daily test, discard and fill with new solution.

Counter Top Sterilizer:

- Daily: Check water level and fill as needed with distilled water.
- Monthly: Empty water and run cleaning cycle (document in logbook), then refill with distilled water.

REMINDER: Always Wear Goggles, Gloves and Fluid Impervious Gown When Working in Scope Cleaning Area.

Exhibit
A64-1

C2.10 APPLYING ELECTROSURGICAL GROUNDING PAD

POLICY:

Electrosurgical grounding pads will be used during monopolar electrocautery.

PURPOSE:

To provide safe electrocautery therapy

PROCEDURE:

Select a well vascularized, muscular site in proximity to procedure. Avoid placement over scars, hairy areas, bony prominences, metal prostheses or near EKG electrodes and cables. **DO NOT APPLY WHERE FLUIDS MAY POOL.**

SITE PREPARATION:

Clean and dry application site as necessary. Application over hairy areas may prevent good skin contact and must not be done.

APPLICATION:

A64-1

Open package just prior to use. Unseal and inspect cord. Remove liner. Avoid excessive contact with adhesive surface prior to application. Begin application at one edge of plate and progress to opposite edge, pressing firmly to ensure good contact of the entire adhesive surface. Insert the cord connector into the proper adapter at the electrosurgical unit.

REMOVAL:

Peel slowly from corner, not from corded tab. Rapid removal may cause skin trauma.

WARNINGS:

- Failure to achieve good skin contact by the entire adhesive surface may result in Electrosurgical burn or poor Electrosurgical performance. If connection to cord is not done properly alarm will sound.
- If higher than normal power settings are requested, a problem may exist. Check patient plate contact and inspect cord and connections. Also inspect active accessories. If problem is not revealed replace Electrosurgical Unit before proceeding.
- Do not reuse or relocate plate after initial application.
- Do not apply plate until patient is positioned. If re-positioning occurs, immediately check plate contact and cord connections before surgery continues.

DO NOT CUT OR MODIFY THE PLATE IN ANY MANNER

- Electrode gel is not required and should not be used.
- Plates are for single patient use only.
- Not sound. Do not connect the plate cable to the machine until the plate has been securely applied to the patient.

Exhibit
A69-1

Digestive Health Center
PERFORMANCE INPROVEMENT

INFECTION MONITORING AND CONTROL

As a physician performing Endoscopy procedures at the **Digestive Health Center,** I will report immediately to Theresa Brandt RN, Center Director, any and all post-procedure infections and/or complications of which I am aware.

I understand that in reporting these incidents, a full report and review of the procedure and cleaning technique will be made.

For the month of ____March_____ 2008:

_____ There were no post-procedure infections and/or complications of which I am aware.

_____ I am reporting the following post-procedure infection(s) and/or complication(s).

Signed _____

Date _____

Exhibit
A69-2

C7.4 CLEANING BETWEEN GI PROCEDURES

POLICY:

Each procedure room and patient care item will be cleaned and/or disinfected appropriately between patients.

PURPOSE:

To prevent cross contamination between patients.

PROCEDURE:

- Between procedures all surfaces in the procedure room will be cleaned with an approved disinfectant solution.
- All disposable drapes or non-disposable linen that has come into contact with the patient or body fluids will be disposed of or changed.
- Biological waste will be placed in a biohazard container.
- All suction liners will be replaced.
- All single use items will be disposed of.

A69-2

Exhibit
A161-1

C4.11 CODE CART INVENTORY

DRAWER 1			
Contents	**Dosage**	**Quantity**	**Expiration Date**
Adenosine	6mg/2mls	3	08/09 (3)
Amiodarone	150mg/3ml	2	05/08 (2)
Atropine (Prefilled)	1mg/10cc	2	02/09(2)
Baby Aspirin	81mg/tab	1 bottle	09/08
Calcium Chloride (Prefilled)	1Gm/10ml	1	04/08
Dextrose 50% (Prefilled)	25Gm/50ml	2	05/08 & 4/08
Digoxin	0.5mg/2ml	1	07/08
Dopamine (Premixed)	400mg in 250ccD5W	1	11/08
Epinephrine (Prefilled)	1mg/10ml	3	12/08
Epinephrine Vial 30ml 1:1000	1mg/ml	1	07/09
Lasix	100mg/10ml	1	04/08
Lidocaine 2% (Prefilled)	100mg/5cc	4	11/08(2) & 04/08(2)
Magnesium Sulfate	1000mg/2ml	1	04/08
Metroprolol	5mg/5ml	3	12/09
Sodium Bicarb (Prefilled)	50mEq/50ml	2	3/09
Valium	10mg/2ml	2	1/09
Verapamil	5mg/2ml	2	04/09

Dopamine: To figure drip rate – use the first 2 digits of the patient's weight in pounds (i.e. **19** for 194lb patient or **9** for a 90lb patient) then subtract 2 from the above number (i.e. **17** or **7** for the above examples). This is the rate in cc/hour which will yield a dose of 5ug/kg/min of dopamine (**17cc/hr** or **7cc/hr** for the above examples!).

To mix Dopamine Drip: 400mg Dopamine in 250cc D_5W yields 1600mcg dopamine/1cc

Use extension tubing with dial regulator to approximate cc/hr

DRAWER 2

Contents	Quantity	Expiration Date
Alcohol Prep	200	N/A
Central Line Kit	1	05/08
IV – 0.9% NS	2/500cc bags	06/08
IV Administration Set	3	N/A
IV Cath (14,20,22)	3 each	N/A
IV Extension Smallbore	3	N/A
IV Extension-Regulator	2	N/A
NS Prefilled Syringes 10cc	3	10/09
Povidine/Betadine Solution	1 Bottle	08/10
Tincture of Benzion	1 Bottle	N/A
Syringes 3cc/6cc	3 each	N/A
Tape 1"	1	N/A
Tourniquet	1	N/A

DRAWER 3

Contents	Quantity	Expiration Date
Endotracheal Tubes/Stylet	2	N/A
#3.0 Cuffed	1	N/A
#4.0 Cuffed	1	N/A
#5.0 Cuffed	1	N/A
#6.0 Cuffed	1	N/A
#6.5 Cuffed	1	N/A
#7.0 Cuffed	1	N/A
#7.5 Cuffed	1	N/A
#8.0 Cuffed	1	N/A
#8.5 Cuffed	1	N/A
CO2 Detector (Southern Anesthesia)	1	07/10
Flashlight	2	N/A
K-Y Jelly	1	9/09
Laryngoscope	1	N/A
Laryngoscope Blades	8 assorted sizes (Millers/Mac)	N/A
Laryngoscope Bulb	1	N/A
Stethoscope	1	N/A
Tongue Depressors	6	N/A

DRAWER 4

Contents	Quantity	Expiration Date
Disposable Ambu Bag w/ Pediatric Mask	1	N/A
Oropharyngeal Airways	7 assorted sizes	N/A
Gauze 4x4	1 Package	N/A
Nasal Cannula	2	N/A
O2 Wrench	1	N/A
Scalpels	12	N/A
Sterile Gloves	7.0 (1) & 7.5/8.0 (2)	N/A
Suction Kits	2	N/A
Suction Tubing	2	N/A
Tubing Connectors & Christmas Trees	2 Each	N/A
Yankquer Suction Tip	1	N/A
Tracheostomy Tray (size 6)	1	04/09
Tracheostomy Tray (size 8)	1	04/09
Rusch QuickTrach	1	12/11

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DRAWER 5

Contents	Quantity	Expiration Date
Adult Oropharyngeal Airways (Sm, Med ,Lg)	1 Each	N/A
Adult Disposable Ambu Bag & Mask	1	N/A
Electrodes/"Red Dots"	8 packages of 3/Bag	03/09
Defibrillator Pads	Box 10(Top of Cart)	03/09
Recorder Paper	5 Boxes	N/A
Scissors/Pick-ups/Tweezers (non-sterile)	1 Each	N/A
Safety Goggles	2	N/A
Sharps Container	1 Small	N/A
"Surevent" Ventilator	2	10/12/12

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Outside Cart		
Defibrillator Unit with ECG Cables and Recorder Paper	1	N/A
Electrodes	2 packages	03/09
Defibrillator Pads	1 box	03/09
V-Vacuum Suction Unit	1 handle/2 containers	N/A
Back Board	1	N/A
O2 Tank with Regulator/Key	1	N/A
Clipboard with Code Flow Sheets	1	
Binder with: Cart Checklist Algorithms Emergency Drug/Supply List	1 each	N/A

Reversal Agents/Room

ROOM #	DRUG	EXPIRATION DATES
1	Narcan 0.4mg Romazicon .5mg/5ml	09/09 05/09
2	Narcan 0.4mg Romazicon .5mg/5ml	09/09 09/09
3	Narcan 0.4mg Romazicon .5mg/5ml	09/09 09/09
4	Narcan 0.4mg Romazicon .5mg/5ml	09/09 05/09

C4.10 CODE CART/DEFIBRILLATOR CHECKLIST

MONTH:_____ **YEAR:** 2008

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
RN Initial																															
Room 3 (Med) Refrigerator Temp (36 to 42 degrees)																															
Nurse Station Refrigerator Temp (36 to 42 degrees)																															
AC Current tested daily once at 200J																															
Cart Plugged In																															
Lock Intact																															
Algorithms Present																															
Suction Machine																															
Back-Board																															
O2 Tank																															
AMBU Bag																															
Battery Back-up tested q Friday (unplugged with 5 discharges) at200J																															
Drawers contents checked each month (Friday)																															
Laryngo-scope Bulb/Battery √ each month (Friday) Trach Tray present Ventilator present																															

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SIGNATURES	INITIALS

LEGEND

H = Holiday

W = Weekend

Lock#_____

Lock#_____

Lock#_____

Exhibit

A187-1

C2.2 CONSCIOUS SEDATION

POLICY:

All physicians providing conscious sedation will be credentialed and approved by the Governing Board to provide conscious sedation. All patients undergoing procedure/surgery under IV conscious sedation will be monitored by a Registered Nurse who has verification of current training in Basic Life Support Certification and/or Advanced Cardiac Life Support Certification.

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PURPOSE:

To ensure approved licensed independent practitioners/staff who possess the expertise to provide safe and appropriate patient care

Definition

Conscious Sedation

According to the JCAHO CAMAC 2001 Sedation and Anesthesia Standards, Conscious Sedation (moderate sedation/analgesia) is "a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular functions are usually maintained."

The term "Conscious Sedation" is not to be interchanged with anesthesia or the administration of an opioid as part of a pain management protocol.

Examples of Conscious Sedation agents are Versed, Valium, Demerol, Morpine, Fentanyl, Nubain, Stadol, and Chloral hydrate.

Sedatives are defined as those agents such as Versed and Valium used to reduce anxiety. When combined with analgesics (opioids - narcotics), the objective is sedation which alters mood, maintenance of consciousness and cooperation, elevation of pain threshold with minimal changes in vital signs, partial amnesia and prompt safe return to activities of daily living.

PROCEDURE:

- The attending physician or anesthetist is responsible for overseeing the administration of conscious sedation.
- An anesthetist or attending physician selects and orders the medications to achieve conscious sedation.
- A written order must be present on the chart for conscious sedation medications.
- The attending physician is responsible for completing a patient assessment immediately prior to administration of conscious sedation and prior to discharge.
- A Registered Nurse will be present to monitor the patient throughout the procedure. A187-1
- All nursing personnel will possess the knowledge and skills to assess, diagnosis and intervene in the event of complications and in accordance with physician orders and Center guidelines. (See Addendum C of this policy.)
- All nurses administering conscious sedation must complete a yearly competency review.

- The Procedure Room/OR Nurse will remain with the patient in the Recovery Room until the first set of vital signs are complete and status report is complete.
- The RN is responsible for the documentation of a patient assessment using the Aldrete scoring tool.
- The RN will assure and reinforce that the patient, family/significant other receive teaching/instructions related to the administration of conscious sedation.
- The Recovery Room Nurse will continue assessing the patient from the time of admission until the patient achieves appropriate discharge criteria.

Monitoring Criteria

- All patients receiving conscious sedation will be continuously monitored.
- Physiological measurements include temperature, respiratory rate, oxygen saturation, blood pressure, cardiac rate, cardiac rhythm-per criteria and patient's level of consciousness.
- Documentation will occur at least once preprocedure, every 5 minutes intra-operatively and every 15 minutes post-operatively.
- Additional chart documentation will also include: Allergies, levels of consciousness, monitoring devices, dosage route, time and effects of sedative medications, any interventions such as oxygen or intravenous therapy and the patient's response, any untoward or significant reactions and resolutions.
- Post-procedure, the patient will be monitored for a minimum of 30 minutes after the last dose of medication assuring that the patient is emerging in a safe manner utilizing the Aldrete scoring system.

Equipment and Support Personnel

- Monitoring Equipment
- Medication and reversal agents
- Suction, airways, positive pressure ventilation devices and supplemental oxygen will be readily available.
- Emergency crash cart with defibrillator and emergency medications must be immediately accessible.
- Provisions for backup personnel who are expert in airway management, and advanced cardiopulmonary resuscitation.

Discharge

An assessment must be done at the completion of each procedure and prior to discharge. The Aldrete Score System will be used to assess the patient's status from admission, during recovery, and until discharge. The attending physician must be notified of any deviation of patient status.

ADDENDUM A

Differences Between Conscious Sedation and Deep Sedation Techniques

Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia
Mood altered	Patient unconscious
Patient responsive and is cooperative	Patient responds to painful stimuli
Vital signs stable	Vital signs labile
Local anesthesia provides analgesia	Pain eliminated centrally
Amnesia may be present	Amnesia always present
Minimum recovery room stay	Occasional prolonged recovery room stay or overnight admission required.
Lower risk of perioperative complications	Higher risk of perioperative complications
Difficult or mentally handicapped patients cannot always be managed	Difficult or mentally handicapped patients are managed easily

The various degrees of sedation/anesthesia defined in the following paragraphs by the Joint Commission occur on a continuum. The patient may progress from one degree to another, based on the medications administered, route and dosage. The determination of patient monitoring and staffing requirements should be based on the patient's acuity and the potential response of the patient to the procedure. (See addendum B for Dosing Guidelines)

- Minimal sedation (anxiolysis)
  A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected;
- Moderate sedation/analgesia ("conscious sedation")
  A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained;
- Deep sedation/analgesia
  A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained; and

- Anesthesia (See Chapter C11 Anesthesia.)
  Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

ADDENDUM B

Dosing Guidelines

COMMON IV DRUGS USED IN CONCIOUS SEDATION			
Drug	**Dosing**	**Onset/Duration**	**Comments**
OPIOID ANALGESICS			
Morphine sulfate	1 to 2mg increments; titrating versus onset time to patient response (The standard against which all other Opioids are measured.)	**Onset:** 1 to 3 minutes **Duration:** 4 to 7 hours	**Respiratory depression:** Monitor respiratory rate and depth continuously; pulse oximetry may show oxygen desaturation before overt signs of distress. Be prepared to assist ventilation with bag-valve-mask device and supplemental O2. **Hypotension:** particularly if the patient has preexisting hypovolemia **Nausea/vomiting:** lethargic patients may need suctioning to clear vomitus from the airway.
Meperidine (Demerol)	Dilute and administer in 10mg increments, titrating versus onset time to patient response (Demerol is 1/10 as potent as morphine)	**Onset:** 1 to 3 minutes **Duration:** 1 to 3 hours	Same as for morphine, but may cause more nausea and vomiting than morphine.
Fentanyl (Sublimaze)	50 to100 mcg 0.06 for prevention of surgical pain. 0.1mg Fentanyl=10 mg Morphine Adults: 2mg/kg (0.02 mg/kg) slow IV Children:> 1 year, 0.01-0.02mg/kg	**Onset of sedative effect:** 1 to 3 minutes **Onset of analgesia:** may not be noted for several minutes. **Duration of analgesic effects:** 30 to 60 minutes **Duration of respiratory depression:** longer than 1 hour unless a reversal agent is used.	Same as for morphine
Stadol (butaphanol tartrate)	1-4mg IM every 3-4 hours, 0.5-2mg IV every 3-4 hours not to exceed 4mg per dose.	**Onset:** Within 2-3 minutes after IV injection, within 10-15 minutes after IM injection, 1-5 minutes after nasal use. **Duration:** 2 to 4 hours	Sedation, headache, vertigo, hallucinations, euphoria, palpitations

COMMON IV DRUGS USED IN CONCIOUS SEDATION			
Benzodiazephines			
Drug	**Dosing**	**Onset/Duration**	**Comments**
Diazepam (Valium)	2.5 to 10mg increments with or without narcotic. (There is a greater individual variation in response, so titrate accordingly.) Reduce dose by 1/3 when opioid is being used concomitantly.	**Onset:** 30 seconds to 5 minutes **Duration:** 2 to 4 hours	Slurred speech and nystagmus precede onset of sleep. Contraindicated in untreated narrow-angle glaucoma; irritating to veins, may cause phlebitis, thrombosis, swelling and local inflammation, especially when used in small veins of the hand or wrist.
Midazolam (Versed)	Adults: Initial dose should be as low as 0.5 to 1mg and should not exceed 2.5mg, IV over 2 minutes. *Titrate slowly to effect, allowing at least 2 minutes between doses to evaluate full effect of drug. Once sedation is achieved, additional doses should be 25% of the dose required to produce the sedative end-point; for maintenance, use 0.25 to 1mg.	**Onset:** 1.5 to 5 minutes **Duration:** maximum effect lasts about 5 minutes, gradually declining over the next 30 to 40 minutes. Gross recovery within 2 hours, but effects may last as long as 6 hours.	May potentiate adverse effects of Opioids including respiratory depression when used in combination. Reduce dose in the elderly and debilitated. Reduce dose in-patients with compromised renal function. *Slurred speech and amnesia are two signs that the patient received an ample amount of Versed.
Reversal Agents			
Drug	**Dosing**	**Onset/Duration**	**Comments**
Naloxone (Narcan)	0.1 to 0.4mg titrated to patient response.	**Onset:** apparent within 2 to 3 minutes **Duration:** depends on the dose and administration route. But repeat doses may be necessary after 1 to 2 hours. If given IM, effects may last longer.	Narcotic antagonist; duration of opioids may exceed the naloxone, so repeated doses may be necessary.

Reversal Agents			
Drug	**Dosing**	**Onset/Duration**	**Comments**
Flumazenil (Romazicon)	0.2mg given over 15 seconds. After waiting 45 seconds, an additional dose of 0.2mg can be given. May be repeated at 60 second intervals up to 1mg.	**Onset:** reversal of benzodiazepine effect evident within 1 to 2 minutes after injection. Peak effect occurs within 6 to 10 minutes. **Duration:** 30 to 60 minutes	Benzodiazephine antagonist; duration of most benzodiazepines exceeds duration of flumazenil, ***a minimum of monitoring for an hour after reversal initiated.*** Resedation may be initiated 20 minutes at a dose of 1mg, given in 0.2mg/minute increments until desired effect is achieved. No more than 3mg is recommended to be given in any 1 hour period.

COMMON IV DRUGS USED IN CONCIOUS SEDATION			
Sedative - Hypnotics			
Drug	**Dosing**	**Onset/Duration**	**Comments**
Versed PO	Children > 12 years: 10mg/2cc; 0.5mg/kg in 5cc nutrasweet grape	**Onset:** 1.5 to 5 minutes	Pre-op for children over the age of 12 months but less than 5 years of age. No patient receives more than 10mg PO.
Chloral Hydrate	Children: 25-75mg/kg PO; 30 minutes prior to procedure	**Onset:** Occurs within 30 minutes to 60 minutes **Duration:** 4 to 8 hours	

ADDENDUM C

RN Staff Criteria

Specific criteria for the Registered Nurse managing the care of a patient receiving conscious sedation include the following:

- Advanced Cardiopulmonary Support (ACLS) is recommended.
- Basic Life Support (BLS) is required.
- Training is required in the recognition of the cardiovascular and respiratory side effects of sedatives, as well as the variability of patient response.
- Successful completion of a basic "Arrhythmia Class" is strongly encouraged.
- The RN administering the medications is knowledgeable in the pharmacology of the medications administered.
- Annual competency based education on conscious sedation is required.